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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,078	12/18/2000	Randy L. Merry	P-8865	4552

27581 7590 10/19/2004

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EXAMINER

NAJARIAN, LENA

ART UNIT PAPER NUMBER

3626

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/740,078	MERRY ET AL.	
	Examiner	Art Unit	
	Lena Najarian	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>20011017</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-7, 10-19, and 22-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 17-20, 26, and 31-34 of U.S. Patent No. 6,442,432 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because "IMD installation and management data" is a form of "IMD data" and a "programmer" may be an "interface device".

3. Claims 8-9 and 25-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 17-20, 26, and 31-34 of U.S. Patent No. 6,442,432 B2 in view of 5,258,906. Kroll et al. (5,258,906) discloses a third party payor computer, generating at least one invoice pertaining to at least one medical apparatus, that the central computer is adapted to generate and

transmit electronically an invoice pertaining to a medical apparatus' operations, and that at least one additional peripheral computer may generate an invoice.

Claim Rejections - 35 USC § 112

4. Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 2 and 3 recite the limitation "the IMD-accessible data" in line 1 of each claim. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-7 and 10, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Kumar et al (6,416,471 B1).

(A) Referring to claim 1, Kumar shows a computerized method of automatically obtaining and distributing data from one or more signal transfer units attached to one or more patients, comprising the steps of (column 1, lines 50-53 of Kumar):

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transmitting via a network communication link signal transfer unit installation and management data pertaining to at least one of the signal transfer units to a programmer communicating with a central computer system external to any patient (column 2, lines 9-12 of Kumar);

routing the signal transfer unit data to the central computer system (column 1, line 67 - column 2, line 3 of Kumar); and

routing the signal transfer unit data to one or more peripheral computer systems (column 1, lines 62-64 of Kumar).

(B) Referring to claim 2, Kumar shows that the signal transfer unit-accessible data comprises physiologic data from the patient (column 2, lines 29-35 of Kumar).

(C) Referring to claim 3, Kumar shows that the signal transfer unit-accessible data comprises device information (Figure 16D and column 36, lines 44-50 of Kumar).

(D) Referring to claim 4, Kumar discloses that the device information comprises at least one of device model number, serial number, hardware, firmware, or software identification patient name, patient contact information, clinician name, and clinician entity (Figure 16D and column 36, lines 44-50 of Kumar).

(E) Referring to claim 5, Kumar discloses a frequency radio link (column 11, lines 46-48 of Kumar).

(F) Referring to claims 6 and 7, Kumar discloses a hybrid link wherein the link comprises a radio frequency link from a signal transfer unit to a network interface, and a secondary network link from the network interface to the computer (Figure 1 of Kumar).

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(G) Referring to claim 10, Kumar discloses a dial up connection (column 13, lines 46-51 of Kumar).

(H) Referring to claim 17, Kumar discloses the step of storing the data in storage means accessible to the remote monitoring station (column 12, lines 46-50 of Kumar).

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 18-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Mann et al. (5,833,623).

(A) Referring to claim 18, Mann discloses a computerized information network system linking one or more IMD programmers to a centralized computer system via a data communication network, said network comprising (column 14, lines 59-61 of Mann):

a first computer accessible by the network, said central computer capable of storing data regarding an IMD (column 18, lines 36-40 of Mann);

at least one network interface to at least one programmer, said network interface being capable of communication with the network (column 1, lines 17-23 of Mann);

at least one additional peripheral computer in data communication with the first computer (column 15, lines 59-62 of Mann).

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(B) Referring to claim 19, Mann discloses wherein the network comprises a direct link between the at least one network interface and the computer (column 1, lines 17-23 of Mann).

(C) Referring to claim 20, Mann discloses that the first computer comprises a supercomputer (column 7, lines 29-33 of Mann).

(D) Referring to claim 21, Mann discloses that the first computer comprises a multi-processor workstation (column 14, line 66 – column 15, line 3 of Mann).

(E) Referring to claim 22, Mann discloses that the first computer comprises a networked or parallel cluster of computers (column 14, lines 59-61 of Mann).

(F) Referring to claim 23, Mann discloses that the data communication is asynchronous (column 14, lines 59-65 of Mann; the Examiner interprets the modem communication to be a form of asynchronous communication).

(G) Referring to claim 24, Mann discloses that the data communication is synchronous (column 14, lines 9-13 of Mann; the Examiner interprets "real time" to be a form of synchronous).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. Claims 11, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. (6,416,471 B1) as applied to claims 1 and 6-7 above, and further in view of Snell (6,249,705 B1).

(A) Referring to claims 11, 14, and 15 Kumar does not disclose that the secondary network link is an area network, wherein the area network is a LAN, and wherein the area network is a WAN.

Snell discloses that the network may be a local area network (LAN) or a wide area network (WAN) (column 6, lines 40-44 of Snell).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Snell within Kumar. The motivation for doing so would have been to allow information about patients to be shared among many programmers (see abstract of Snell).

12. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. (6,416,471 B1) as applied to claims 1 and 6-7 above, and further in view of Nappholz et al. (5,720,770).

(A) Referring to claims 12 and 13, Kumar does not disclose that the secondary network communication link comprises an asynchronous link and that the secondary network communications link comprises a synchronous link.

Nappholz discloses an asynchronous link and a synchronous link (column 1, lines 17-20, column 4, line 3, and column 7, lines 23-27).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Nappholz within Kumar. The motivation for

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doing so would have been to accommodate user preferences in communication links technologies.

13. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. (6,416,471 B1) as applied to claim 1 above, and further in view of Mann et al. (5,833,623).

(A) Referring to claim 16, Kumar does not disclose that the signal transfer units comprise one or more of a pacemaker, a PCD pacemaker/cardioverter/defibrillator, an oxygen sensing device, a nerve stimulator, a muscle stimulator, a drug pump, or an implantable monitoring device.

Mann et al. discloses implantable cardiac pacemakers, implantable cardioverter/defibrillators (ICD's), heart monitors, or any other medical device that provides diagnostic data for subsequent retrieval and display (column 1, lines 12-18 of Mann).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Mann within Kumar. The motivation for doing so would have been to allow a physician to rapidly and accurately retrieve, evaluate, and process diagnostic data stored by the implantable device (column 1, lines 19-22 of Mann).

14. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. (6,416,471 B1) as applied to claim 1 above, and further in view of Kroll et al. (5,258,906).

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(A) Referring to claim 8, Kumar does not disclose that the one or more peripheral computer comprise at least one of a supplier computer, a business system computer, an accounts payable computer, an accounts receivable computer, a clinician computer, or a third party payor computer.

Kroll discloses a third party payor computer (column 3, lines 36-39 of Kroll).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Kroll within Kumar. The motivation for doing so would have been to store the third party information (column 3, lines 36-39 of Kroll).

(B) Referring to claim 9, Kumar does not disclose the step of generating from at least one peripheral computer at least one invoice pertaining to at least one IMD, the invoice being derived at least in part from the IMD data.

Kroll discloses generating at least one invoice pertaining to at least one medical apparatus, the invoice being derived at least in part from the medical apparatus data.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Kroll within Kumar. The motivation for doing so would have been to automatically invoice and credit the payor (column 1, lines 12-14 of Kroll).

15. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann et al. (5,833,623) as applied to claim 18 above, and further in view of Kroll et al. (5,258,906).

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(A) Referring to claim 25, Mann does not disclose that the central computer is adapted to generate and transmit electronically an invoice pertaining to an IMD programmer event.

Kroll shows that the central computer is adapted to generate and transmit electronically an invoice pertaining to a medical apparatus' operations (column 5, lines 49-62 of Kroll).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Kroll within Mann. The motivation for doing so would have been to automatically invoice the user (column 1, lines 19-20 of Kroll).

(B) Referring to claim 26, Mann does not disclose that at least one additional peripheral computer may generate an invoice.

Kroll discloses the generation of an invoice (column 3, line 67 – column 4, line 4 of Kroll).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Kroll within Mann. The motivation for doing so would have been to automatically invoice the user (column 1, lines 19-20 of Kroll).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a method and apparatus for providing patient care (US-6,398,727 B1); a method and apparatus for

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electronically accessing and distributing personal health care information and services in hospitals and homes (US-5,867,821 A); a system for treatment of neurological disorders (US-6,016,449 A); and a health monitoring and diagnostic device and network-based health assessment and medical records maintenance system (US-6,602,469 B1).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is (703) 305-0260. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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